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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/847,081 | 05/02/2001 | Marco Busch | Mo-6314/LeA 34,326 | 7196 |

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BAYER CORPORATION
PATENT DEPARTMENT
100 BAYER ROAD
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EXAMINER

KALLIS, RUSSELL

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 08/07/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,081

Applicant(s)

BUSCH ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 and 25-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 19, 25-26, 28-32, 35-36, and 38 drawn to a nucleic acid, promoter, vector, method of transformation, transformed host cells, and transformed plants classified in class 435, subclass 468, for example.
- II. Claims 7 and 28, drawn to a vector comprising a promoter, classified in class 536, subclass 24.1 for example.
- III. Claims 14-15, drawn polypeptides, classified in class 530, subclass 350, for example.
- IV. Claims 16-17, drawn to an antibody, classified in class 530, subclass 387.1, for example.
- V. Claim 18, drawn to a method of chemical synthesis, classified in class 435, subclass 91.5, for example.
- VI. Claim 18, drawn to a method of hybridization, classified in class 435, subclass 6, for example.
- VII. Claim 18, drawn to a method of PCR amplification, classified in class 435, subclass 91.2, for example.
- VIII. Claims 20-21 and 33-34, drawn to a method of chemical screening, classified in class 435, subclass 7.4, for example.
- IX. Claims 27 and 37, drawn to a method of mutagenesis classified in class 435, subclass 441, for example.

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Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the polynucleotides of Group I and the promoter and vector of Group II, have different structure and function.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the polynucleotides of Group I and the polypeptides of Group III, have different composition, structure, and function.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the polynucleotides of Group I and the antibodies of Group IV, have different composition, structure, and function.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the different inventions, the polynucleotides of Group I and the method of chemical synthesis of DNA of Group V, differ in that the polynucleotides can be synthesized by another method other than the method of chemical synthesis of Group V, such as a PCR method.

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Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the different inventions, the polynucleotides of Group I and the method of hybridization of Group VI, differ in that the polynucleotides can be made by another method other than the hybridization method of Group VI, such as a PCR method.

Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the different inventions, the polynucleotides of Group I and the method of PCR amplification of Group VII, differ in that the polynucleotides of Group I can be made by another method other than the method of PCR amplification of Group VII, such by a hybridization method.

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of transformation of Group I and the method of chemical screening of Group VIII differ in starting materials, method steps and end products, Also, the polynucleotides of Group I can not be used in the method of chemical screening of Group VIII.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different inventions, the polynucleotides of Group I and the method of mutagenesis of Group IX, differ in that the polynucleotides of Group I can be used in another method other than the method of mutagenesis of Group IX, such as a hybridization method.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the polypeptides of Group III, have different composition, structure, and function.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the antibody of Group IV, differ in composition, structure, and function.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the method of chemical synthesis of a cDNA of Group V, differ in that the promoter and vector can not be used or produced by the method of chemical synthesis of a cDNA.

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Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the method of hybridization of Group VI, differ in that the promoter and vector can not be made or used in the method of hybridization for generating a cDNA.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the method of PCR amplification of Group VII, differ in that the promoter and vector can not be made or used in the method of PCR amplification of a cDNA.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the method of chemical screening of Group VIII, differ in that the promoter and vector of Group II can not be used in the chemical screening method of Group VIII.

Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the promoter and vector of Group II and the method of mutagenesis of Group IX,

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differ in that the vector and promoter of Group II can not made or used in the method of mutagenesis of a cDNA.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the polypeptides of Group III and the antibodies of Group IV, have different structure and function.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Group III can not be used in the method of chemical synthesis of a cDNA of Group V.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Group III can not be used in the method of hybridization for generating a cDNA of Group VI.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Group III can not be used in the method of PCR amplification of a cDNA of Group VII.

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Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Group III can not be used in the method of chemical screening of Group VIII.

Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Group III can not be used in the method of mutagenesis of a cDNA of Group IX.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Group IV can not be used in the method of chemical synthesis of a cDNA of Group V.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Group IV can not be used in the method of hybridization of Group VI.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Group IV can not be used in the method of PCR amplification of Group VII.

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Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Group IV can not be used in the method of chemical screening of Group VIII.

Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Group IV can not be used in the method of mutagenesis of a cDNA of Group IX.

Inventions V, VI, VII, VIII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different starting materials, method steps, and products.

If Applicant elects Group I, Applicant is required to elect a single nucleic acid sequence of SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 5. If Applicant elects Group III or IV, Applicant is required to elect a single amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, or SEQ ID NO: 6. This requirement is not to be construed as a requirement for an election of species, since each of the nucleic acid sequences or amino acid sequences recited in alternative form is not a member of a single structurally and functionally related genus, but rather constitutes an independent and patentably distinct invention. Separate searches and considerations would be required for examination of each of the nucleic acid sequences.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and because the search required for one of the groups is not required for another, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 308-0009.

Russell Kallis Ph.D.
August 2, 2002



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